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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/530,663	Applicant(s) CHIANG ET AL.	
	Examiner Stuart Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-31,45,46 and 54-77* is/are pending in the application.

4a) Of the above claim(s) *1-28,32-44 and 47-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-31,45,46 and 54-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 54-77 were added as requested in Paper no. 18, filed July 11, 2002. Claims 1-77 are pending.

Applicant's election of Group V, claims 29-31 and 45-46, in Paper No. 18 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 54-77 belong to Group V.

Claims 1-28, 32-44, and 47-53, are withdrawn from consideration for being drawn to non-elected inventions.

Claims 29-31, 45-46, and 54-77 will be examined on their merits.

Claim Objections

Objection is made to claims 57, 65, 75, and 77 which specifies DNA sequences by the terms Box P, Box A and Box L. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 45, 46, 56, 57, 62, 64, 65, 67 and 73-77 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 45, 46, and 56 are indefinite in the recitation "transcriptional regulatory region". Applicant has not established the metes and bounds of the transcriptional regulatory region. It is unclear what type of DNA sequence is encompassed by this term and the specification fails to further define or clarify the use of this term.

Claim 31 is indefinite in the recitation of "directs expression of a linked segment to the xylem", given that the use of "to the xylem" suggests that the regulatory sequence is regulating transport of the molecule, rather than an indication of transcription at that site. Amendment of the claims to read --in the xylem-- would overcome the rejection.

Claim 54 is indefinite in the recitation "gene of interest", since it is unclear what criteria would be used to determine which genes would be of interest. Amendment of the claim to delete "of interest" would overcome the rejection.

Claim 56 requires the article "a" before "promoter fragment".

Claims 56, 74, 76, and 77 are indefinite in the recitation "promoter fragment" or "gene promoter". Applicant has not established the metes and bounds of a promoter fragment or gene promoter. It is unclear what type or length of DNA sequence is encompassed by these terms, and a fragment can be as little as one nucleotide.

Claims 57, 65, 75, and 77 are indefinite in the recitation "a cis-acting element". Applicant has not established the metes and bounds of a cis-acting element. It is unclear what

type or length of DNA sequence is encompassed by this term, and the specification fails to define or clarify the use of this term.

Claims 62, and 64, are indefinite in the recitation "transcriptional control region". Applicant has not established the metes and bounds of a transcriptional control region. It is unclear what type or length of DNA sequence is encompassed by this term.

Claim 67 is indefinite in the recitation "4CL promoter", since it is unclear what that is.

Claims 73, and 74 are indefinite in the recitation "5' flanking region". Applicant has not established the metes and bounds of a 5' flanking region. It is unclear what type or length of DNA sequence is encompassed by this term.

Claims 57, 65, 75, and 77 are an improper Markush group as it fails to follow the prescribed format as noted in MPEP 2173.05(h). In claim 57, Applicant has included the phrase "at least one of" which is improper and in claims 57, 65, 75, and 77, Applicant has included the phrase "combinations thereof" which is also improper.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-31, 45-46, 54, 56-62, 64-70, and 73-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of any plant 4-coumarage Co-enzyme A ligase gene, or a 4-coumarage Co-enzyme A ligase gene from aspen, an expression cassette comprising a transcriptional control region of any 4-coumarage Co-enzyme A ligase gene operably linked to a DNA coding region wherein the transcriptional regulatory region is a promoter fragment, and method of expressing a DNA segment in the xylem of a plant comprising introducing an expression cassette comprising a transcriptional control region of any 4-coumarage Co-enzyme A ligase operably linked to a DNA segment, an isolated and purified DNA molecule consisting of at least one of a cis-acting element, a polynucleotide comprising a sequence as shown in SEQ ID NO:5, wherein SEQ ID NO:5 is characterized by having promoter activity wherein the promoter is encompassed by 5' flanking region and a gene promoter comprising a polynucleotide sequence shown as SEQ ID NO:5 or a promoter fragment thereof.

The Applicants isolated an aspen 4-coumarate Co-enzyme A ligase promoter from the Pt4CL1 genomic clone of SEQ ID NO:5 and demonstrated that it specified expression in xylem tissues of the leaf mid-rib and root of tobacco plants but they do not identify structural features unique to Pt4CL1 genomic clone promoter of SEQ ID NO:5 or any 4-coumarate Co-enzyme A ligase promoter from aspen nor from any plant. In addition, the Applicants do not identify the functional domains of the promoter of SEQ ID NO:5 nor do they describe the functional or characteristic domains from any of the following; a transcriptional regulatory region, a transcriptional control region, a 5' flanking region, a promoter fragment, a gene promoter or any

cis-acting elements, all of which are recited in the claims but which Applicant has not described. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See Fiers vs. Sugarno, 25 USPQ2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Given the lack of description for any 4-coumarate Co-enzyme A ligase promoter or given the lack of description for any of the following recited phrases; a transcriptional regulatory region, a transcriptional control region, a 5' flanking region, a promoter fragment, a gene promoter or any cis-acting elements, it remains unclear what features identify any of the before recited regulatory regions. Since none of the before-mentioned regulatory regions have been described by specific structural features, the specification fails to provide an adequate written description to support the generic claims.

Claims 29-31, 45-46, 54, 56-62, 64-70, and 73-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated and purified DNA molecule comprising the transcriptional regulatory region or a transcriptional control region, both of which as shown in SEQ ID NO:5, which is characterized by having promoter activity that expresses GUS in the xylem of the stem, of the leaf mid-rib and in the root of transformed tobacco plants, does not reasonably provide enablement for claims broadly drawn

to an isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of any plant 4-coumarage Co-enzyme A ligase gene, or a 4-coumarage Co-enzyme A ligase gene promoter from aspen, an expression cassette comprising a transcriptional control region of any 4-coumarage Co-enzyme A ligase gene operably linked to a DNA coding region wherein the transcriptional regulatory region is a promoter fragment, and method of expressing a DNA segment in all the xylem cells of any plant comprising introducing an expression cassette comprising a transcriptional control region of any 4-coumarage Co-enzyme A ligase operably linked to a DNA segment, an isolated and purified DNA molecule consisting of at least one of a cis-acting element, a polynucleotide comprising a sequence as shown in SEQ ID NO:5, wherein SEQ ID NO:5 is characterized by having promoter activity wherein the promoter is encompassed by any 5' flanking region and a gene promoter comprising a polynucleotide sequence shown as SEQ ID NO:5 or a promoter fragment thereof for the purpose of expressing any gene in the xylem tissue of any plant for engineering agronomically desirable traits selected from the group consisting of altered lignin content, increased or decreased coniferyl and sinappyl alcohol units in the lignin structuree, altered cellulose content, altered growth, or altered cellulose content and combinations thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Applicants isolated a 4-coumarate Co-enzyme A ligase (4CL) cDNA from a cDNA library made from RNA isolated from the cambium of quaking aspen (*Populus tremuloides* Michx). One of the cloned cDNA's was designated as Pt4CL1 (page 12, line 21). Applicants isolated the corresponding encoding genomic sequence using the Pt4CL1 cDNA and subcloned

ca. 2.3 kb 5' flanking region of the Pt4CL1 coding region which was later used in a promoter deletion study (page 27, line 7-13). Three cis-acting elements box P (SEQ ID NO:15), box A (SEQ ID NO:16) and box L (SEQ ID NO:17) were isolated within 1 kb 5' flanking region(page 28, lines 3-7).

The Applicants have only expressed GUS in the stem xylem, the mid-rib xylem and the root xylem using the full length SEQ ID NO:5 but have not reduced to practice using any 4-coumarate Co-enzyme A ligase promoter or any of the claimed fragments such as "a transcriptional regulatory region", a "transcriptional control region", a "cis-acting element", a "5' flanking region", a "promoter fragment", a "gene promoter" or a fragment of SEQ ID NO:5 which are operably linked to a polynucleotide encoding an enzyme involved in any of the processes as mentioned in claims 58, or 66. In addition, the Applicants have not demonstrated or reduced to practice, that any of the above-claimed regions will specify expression of an operably linked gene of interest in all the xylem cells of the plant as claimed in claim 76 (including the xylem of the floral organs, or the xylem of the leaf blade). In addition, Applicants have stated in the specification that the "Pt4CL2 promoter did not direct GUS expression in vascular and xylem tissues in the stem and the leaf of [Pt4CL23p-GUS] transgenic plants" (page 30, lines 18-20). Applicants conclude that 4CL isoforms have distinct roles which reflect the specific expression patterns of the different 4Cl isoforms (page 31, lines 3-21).

The claims are broadly drawn to fragments of DNA such as "a transcriptional regulatory region", a "transcriptional control region", a "cis-acting element", a "5' flanking region", a "promoter fragment", a "gene promoter" or a fragment of SEQ ID NO:5. The instant specification, however, fails to provide guidance for which base of SEQ ID NO:5 or which base

or bases constitute any of the recited regions. The specification fails to provide guidance for which base can be deleted and which regions of the sequence can tolerate additions, base-substitutions or recombinations and still be a functional promoter.

Non-coding nucleic acid sequences that exhibit base pair deletions, substitutions or rearrangements, cannot be expected to maintain their promoter or enhancer activity. Izawa et al (1993, J. Mol. Biol. 230 :1131-1144) teach the nucleotides flanking the G-box (CACGTC) and C-box (GACGTC) hexameric cores were shown to affect protein binding activity and specificity of bZIP transcription factors (page 1132, bottom of right column; page 1134, bottom of left column). Hao, et al (1998, The J. of Biological Chemistry 273 (41): 26857-26861) investigated the binding activities of ethylene-responsive element-binding proteins (EREBP) to their cis-element GCC box (AGCCGCC). Creating base-pair substitutions within the GCC box modulates binding specificity, implying that different positions within the GCC box are important for differential binding by different EREBP's, in particular, substituting T's for the two G's eliminates binding completely (*supra*, pages 26857, abstract and 26860, left column, 2nd paragraph).

Even though Applicants are not claiming any intronic regions, the mechanism by which intronic regions facilitate transcription is the same as 5' promoter regions. Not only are DNA sequences located 5' to the translation start site (ATG) sensitive to base changes, but in some instances, intronic regions have been shown to be necessary for proper gene expression. Busch et al (1999, Science 285:585-587) and Lohmann et al (2001, Cell 105 :793-803) teach *LEAFY* (*LFY*) and *WUSCHEL* (*WUS*), which have been shown to be transcription factors that together activate proper *AGAMOUS* (*AG*) expression, do so by binding to the second intron of the *AG*

gene. A two base-pair mutation within the binding site of either *LFY* or *WUS* eliminates binding of either *LFY* or *WUS*, respectively (Busch et al (supra) page 587 left column, 2nd paragraph; Lohmann et al (supra) page 799, bottom and top of left and right columns) and changes the temporal and spatial *AG* expression pattern.

In addition, using a promoter isolated from one species of plant would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant. Oommen et al (1994, The Plant Cell 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavone reductase promoter expressed in vegetative tissues and in reproductive organs whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants (abstract).

Given the unpredictability of determining the expression profile of a multitude of nucleic acid fragments that are encompassed in the recitations "a transcriptional regulatory region", a "transcriptional control region", a "cis-acting element", a "5' flanking region", a "promoter fragment", a "gene promoter" or a fragment of SEQ ID NO:5, and given the unpredictability of replicating a specific expression profile in plants other than tobacco, for the reasons stated above; and given the lack of guidance and examples of isolating a specific fragment whose promoter acitivity duplicates the expression profile of SEQ ID NO:5 for the reasons stated above; and give the state of the art that teaches minor base deletions, additions, and substitutions disrupts the normal promoter acitivity of a cis-acting element as discussed above, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 65, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Grattapaglia et al (1995, WO9519697).

The claims are drawn to an isolated and purified DNA molecule comprising a promoter fragment consisting of at least one of a cis-acting element, a box P sequence motif, a box A sequence motif or a box L sequence motif, and combinations thereof.

Grattapaglia et al teach a DNA sequence that exhibits 100% sequence identity to the claimed box A sequence and as such anticipates the claimed invention.

Claims 57, 65, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Baxter-Lowe, L.A. (1996, U.S. Patent 5,545,526).

The claims are drawn to an isolated and purified DNA molecule comprising a promoter fragment consisting of at least one of a cis-acting element, a box P sequence motif, a box A sequence motif or a box L sequence motif, and combinations thereof.

Baxter-Lowe teaches a DNA sequence that exhibits 100% sequence identity to the claimed box L sequence and as such anticipates the claimed invention.

Claims 29, 31, 45-46, 54, 56-59, 61-62, 64-66, and 76-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Oommen et al (1994, The Plant Cell 6:1789-1803).

The claims are drawn to an isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of a plant 4-coumarate Co-enzyme A ligase gene wherein the transcriptional regulatory region is a promoter fragment and wherein the DNA segment directs expression to the xylem of a plant and wherein the promoter fragment is a cis-acting element, an expression cassette comprising a transcriptional control region of a 4-coumarate Co-enzyme A ligase gene operably linked to an open reading frame or a gene of interest, a method of expressing a DNA segment in the xylem of a plant comprising introducing an expression cassette comprising a transcriptional control region of a 4-coumarate Co-enzyme A ligase gene operably linked to a DNA segment into cells of a plant, and a gene promoter comprising a polynucleotide sequence shown as SEQ ID NO:5 or a promoter fragment thereof wherein the promoter fragment is a cis-acting element.

In instances where Applicant has recited "a transcriptional regulatory region", a "transcriptional control region", a "cis-acting element", a "promoter fragment", a "gene promoter" or a fragment of SEQ ID NO:5, these phrases read on one base pair.

Given the above stated interpretation, Oommen et al teach a DNA sequence operably linked to a GUS gene (page 1801, 4th paragraph, righ column) that expresses in the vascular cylinder of alfalfa plants which comprises xylem tissue (page 1793, right column, 1st paragraph). The DNA sequence of Oommen et al comprise at least one base pair that is essential for the proper expression and would be found in Applicant's claimed invention, and as such, Oommen et al anticipate the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 29, 31, 45, 46, 54, 56-59, 61, 62, 64-70, 76, and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Xue et al (filed Sept. 9, 1996 U.S. Patent 6,420,629)

The claims are drawn to an isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of a plant 4-coumarate Co-enzyme A ligase gene wherein the transcriptional regulatory region is a promoter fragment and wherein the DNA segment directs expression to the xylem of a plant and wherein the promoter fragment is a cis-acting element, an expression cassette comprising a transcriptional control region of a 4-coumarate Co-enzyme A ligase gene operably linked to an open reading frame or a gene of interest, a method of expressing a DNA segment in the xylem of a plant comprising introducing an expression cassette comprising a transcriptional control region of a 4-coumarate Co-enzyme A ligase gene operably linked to a DNA segment into cells of a plant, and a gene promoter comprising a polynucleotide sequence shown as SEQ ID NO:5 or a promoter fragment thereof wherein the promoter fragment is a cis-acting element. The Applicants also claim an isolated and purified DNA molecule and an expression cassette comprising a DNA segment comprising a

transcriptional regulatory region of a plant 4-coumarate Co-enzyme A ligase gene wherein a coding region is expressed in the plant xylem for engineering agronomically desirable traits such as altered cellulose content.

Xue et al teach an isolated DNA molecule and expression cassette comprising a 4CL promoter operably linked to an UDPG-PPase gene that is expressed in tobacco and altered the cellulose content. The disclosed promoter fragment would inherently contain "a transcriptional regulatory region", a "transcriptional control region", a "cis-acting element", a "promoter fragment", a "gene promoter" or a fragment of SEQ ID NO:5 and as such the claimed invention is anticipated by Xue et al.

Claims 30, 55, 63, and 71-75 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:5 that specifies expression in xylem cells and further comprises 5' flanking DNA, a cis-acting element, and a box P, A, or L sequence motif.

Claims 55 and 63 are objected to for depending on rejected base claims but would be allowable if rewritten in independent form.

Claims 71 and 72 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

August 28, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600